

### **INTRODUCTORY COMMENTS**

Claims 50-55 and 63-79 were pending in the subject application for the final Office Action mailed on March 9, 2007. Each of the pending claims has been rejected on various grounds. In view of the following amendments and remarks, reconsideration and allowance of the subject application are hereby requested.

## **REMARKS**

### **Claim Rejections – 35 USC §102**

Claims 50-55 and 63-79 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,063,088 to Winslow (hereafter “the ‘088 patent”). It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

The Applicant notes that the ‘088 patent does not constitute prior art to the subject application under 35 U.S.C. §102(b). Specifically, the subject application has a priority date stemming from U.S. Application Serial No. 09/181,353, now U.S. Patent No. 6,174,311, of October 28, 1998. However, the ‘088 patent was not published or patented until May 16, 2000. The Applicant reserve the right to challenge the assertion that the ‘088 patent constitutes prior art to the subject application. Nevertheless, as set forth below, the Applicant submits that the claims 50-55 and 63-79 are patentable over the ‘088 patent.

As an initial matter, the Applicant notes that claims 50, 55, 66, 67, 68 and 71 have been amended to more clearly define the present invention, and claims 54, 64, 66, 72, 74 and 76 have been amended in view of the amendments incorporated into other claims and/or to correct one or more informalities.

### **Independent Claim 50 and Dependent Claims 51-54, 63 and 64**

Independent claim 50 has been amended and is now directed to a nerve retractor assembly comprising a retractor blade and a retractor body provided with “first and second enlarged edges extending in an axial direction and defining a channel therebetween” adapted to engagingly receive the retractor blade, with “the retractor blade engaged with the first and second enlarged edges to maintain the retractor blade in a predetermined position relative to the retractor body”, and with “the channel being open in lateral direction between the first and second enlarged edges and the retractor blade being shaped to provide an unobstructed view of a

retracted area of a surgical site.” Support for the amendments to independent claim 50 are found, for example, at page 24, line 30 to page 25, line 20, page 26, lines 3-7, and in Figures 28-30.

The Office Action indicates that the ‘088 patent discloses “a spinal assembly retractor (120, Fig. 3) having a retractor blade portion (204), in a channel (218) that provides an unobstructed view and is adapted to engagingly receive the retractor blade in use.” (See page 2 of the Office Action). As an initial matter, it is respectfully submitted that the drill bit 204 is not a “retractor blade”, as would be appreciated by those having skill in the art. Instead, the ‘088 patent teaches that the drill bit 204 is structured to “form a generally circular bore in the bone structures.” (See column 6, line 67). Moreover, to the extent that the drill bit 204 is inserted through the retractor 100, which retracts the tissue at the surgical site and distracts the adjacent vertebral bodies before the drill bit 204 is positioned within the retractor 100, the Applicant submits that the drill bit 204 does not retract anything. Accordingly, the ‘088 patent does not teach, suggest or disclose a retractor blade, as that feature is set forth in the subject application and recited in independent claim 50.

Additionally, even assuming arguendo that the drill bit 204 could be construed as a retractor blade, independent claim 50 is still patentably distinguishable over the ‘088 patent. Notably, no element of the retractor 100, including either the retractor sleeve 102 or the drill extension sleeve 206, includes “first and second enlarged edges extending in an axial direction and defining a channel therebetween”, with “the retractor blade engaged with the first and second enlarged edges to maintain the retractor blade in a predetermined position relative to the retractor body”. Notably, the drill bit 204 is not engaged with first and second enlarged edges of any component or element of the retractor 100 to maintain the drill bit in a predetermined position relative to a retractor body. Furthermore, no component or element of the retractor 100 defines a channel that is “open in lateral direction” between first and second enlarged edges, with the open channel and the retractor blade being shaped “to provide an unobstructed view of a retracted area of a surgical site.” To the contrary, the passageway 104 of the retractor sleeve 102 is entirely enclosed, and the drilling instrument 200 fills the passageway 104. Accordingly, the retractor 100 does not provide an unobstructed view along the drill bit 204 of a retracted area of a surgical site. Instead, the drilling instrument 200 is positioned within the passageway 104 of the

retractor sleeve 102 and obstructs the view into the passageway 104, and which also obstructs the view of any area of a surgical site which is retracted by the retractor sleeve 102. Additionally, as illustrated in Figures 13-17, the retractor arms 120 are inserted between the adjacent vertebrae V<sub>1</sub>, V<sub>2</sub>, until the distal end of the retractor sleeve 102 contacts the vertebrae V<sub>1</sub>, V<sub>2</sub>, consequently blocking any view of a retracted area within the passageway 104.

For at least these reasons, the Applicant submits that the '088 patent does not teach or suggest each of the elements and features recited in independent claim 50, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 50 as being anticipated by the '088 patent and request allowance of the same. Each of the claims 51-54 and 63-64 depends either directly or indirectly from independent claim 50 and is submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 50.

**Independent Claim 55 and Dependent Claims 65-70**

The Applicants have amended independent claim 55 to recite “a retractor body including a channel and a first supporting member and a second supporting member, the first and second support members extending in an axial direction and positioned on opposite sides of the channel”, and a “first retractor pin being attached to the first supporting member” and a “second retractor pin received for movement within the second supporting member” and with “the channel being open in lateral direction between the first and second support members to provide an unobstructed view of a retracted area of a surgical site.” Support for the amendments to independent claim 55 are found, for example, at page 24, line 30 to page 25, line 20, page 26, lines 3-7, and in Figures 28-30.

With regard to the '088 patent, the Office Action asserts that the first and second rails 106 extending along the retractor sleeve 102 are used for attaching a retractor pin 110. Even assuming arguendo that the passageway 104 extending through the retractor sleeve 102 comprises “a channel” and that the rails 106 constitute “support members”, the passageway 104 is clearly not “open in lateral direction” between the rails 106 “to provide an unobstructed view of a retracted area of a surgical site”, as recited in independent claim 55.

Rather, the rails 106 extend longitudinally along an outer surface of the retractor sleeve 102, and the passageway 104 of the retractor sleeve 102 is entirely enclosed. Accordingly, the passageway 104 of the retractor sleeve 102 is not “open in lateral direction”, and does not “provide an unobstructed view of a retracted area of a surgical site”. Additionally, the ‘088 patent does not disclose a first retractor pin that is attached to a first supporting member and a second retractor pin that is received for movement within the second supporting member. To the contrary, the ‘088 patent discloses that each of the anchoring members 110 is structured “to be engaged by a driving member . . . to rotate and advance the anchoring member 110 . . .” and “is biased proximally by coil spring 116 . . .” (See column 6, lines 4-10). Therefore, each of the anchoring members 110 is free to slide within the openings 108, with neither of the anchoring members 110 being attached to either of the rails 106.

For at least these reasons, the Applicants submit that the ‘088 patent does not teach or suggest each of the elements and features recited in independent claim 55, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 55 as being anticipated by the ‘088 patent and request allowance of the same.

Each of the claims 65-70 depends either directly or indirectly from independent claim 55 and is submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 55. Moreover, dependent claims 65-70 are patentable over the ‘088 patent for additional reasons as well. For example, claim 67 recites that the first and second supporting members define “axially extending edges”, and that the retractor blade is “engaged with the axially extending edges to maintain the retractor blade in a predetermined position relative to the retractor body”. Notably, the ‘088 patent does not disclose any element or structure that could be properly construed as a retractor blade which is engaged with axially extending edges of the rails 106 to maintain the retractor blade in a predetermined position. Additionally, claim 68 recites that “the first and second supporting members define axially extending edges that are adapted to engage the retractor blade to maintain the retractor blade within the channel”. Once again, the ‘088 patent does not disclose any element or structure that could be properly construed as a retractor blade engaged with axially extending edges of the rails 106 to maintain the retractor blade within the passageway 104 of the retractor sleeve 102.

**Independent Claim 71 and Dependent Claims 72-79**

The Applicants have amended independent claim 71 to recite a retractor body having a support portion including “at least one support member defining a channel and having an enlarged edge extending in an axial direction along the channel”, “a retractor blade received within the channel and engaged with the enlarged edge such that the retractor blade is held in a predetermined position relative to the retractor body by the at least one support member”, and with “the retractor blade having a shape complementary to a shape of the support portion and the channel being open in lateral direction to provide an unobstructed view of a retracted area of a surgical site.” Support for the amendments to independent claim 55 are found, for example, at page 24, line 30 to page 25, line 20, page 26, lines 3-7, and in Figures 28-30.

As indicated above with regard to independent claim 50, even assuming *arguendo* that the drill bit 204 could be construed as a retractor blade, independent claim 71 is still patentably distinguishable over the ‘088 patent. Notably, no element of the retractor 100, including either the retractor sleeve 102 or the drill extension sleeve 206, includes “at least one support member having an enlarged edge” that extends in an axial direction along a channel, and with “a retractor blade received within the channel and engaged with the enlarged edge such that the retractor blade is held in a predetermined position relative to the retractor body by the at least one support member”. Notably, the drill bit 204 is not engaged with an enlarged edge of any component or element of the retractor 100 to maintain the drill bit in a predetermined position relative to a retractor body. Furthermore, no component or element of the retractor 100 defines a channel that is “open in lateral direction” between first and second enlarged edges, with the open channel and the retractor blade being shaped “to provide an unobstructed view of a retracted area of a surgical site.” To the contrary, the passageway 104 of the retractor sleeve 102 is entirely enclosed, and the drilling instrument 200 fills the passageway 104. Accordingly, the retractor 100 does not provide an unobstructed view along the drill bit 204 of a retracted area of a surgical site. Instead, the drilling instrument 200 is positioned within the passageway 104 of the retractor sleeve 102 and obstructs the view into the passageway 104, and also obstructs the view of any area of a surgical site which is retracted by the retractor sleeve 102. Additionally, as illustrated in Figures

13-17, the retractor arms 120 are inserted between the adjacent vertebrae V<sub>1</sub>, V<sub>2</sub>, until the distal end of the retractor sleeve 102 contacts the vertebrae V<sub>1</sub>, V<sub>2</sub>, consequently blocking any view of a retracted area within the passageway 104.

For at least these reasons, the Applicants submit that the '088 patent does not teach or suggest each of the elements and features recited in independent claim 71, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 71 as being anticipated by the '088 patent and request allowance of the same.

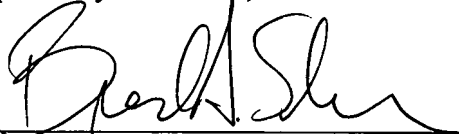
Each of the claims 72-79 depends either directly or indirectly from independent claim 71 and is submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 71. Moreover, dependent claims 72-79 are patentable over the '088 patent for additional reasons as well. For example, claim 79 recites "wherein the retractor blade includes a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space." Even assuming arguendo that the drill bit 204 could be construed as a "retractor blade", the drill bit 204 clearly does not include a distractor tip sized and shaped for distraction of an intervertebral space. Rather, the '088 patent discloses that the drill bit 204 is configured to form a bore between the vertebral bodies, and not to distract the disc space. Additionally, the opposed retractor arms 120 distract the intervertebral space before the drill bit 204 engages the vertebral bodies. Moreover, the anchoring members 110 engage each of the adjacent vertebral bodies after the retractor arms 120 are inserted therebetween, thereby fixing the vertebral bodies relative to each other and prohibiting additional distraction of the intervertebral space.

## CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 50-55 and 63-79.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

Brad A. Schepers  
Reg. No. 45,431  
Krieg DeVault LLP  
One Indiana Square, Suite 2800  
Indianapolis, Indiana 46204-2079  
(317) 238-6334 (voice)  
(317) 238-6371 (facsimile)